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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,403

10/03/2003

Paul J. Hindrichs

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/678,403

Applicant(s)

HINDRICHS ET AL.

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-36, 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/04, 10/04</u> <u>11/18/04, 4/12/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group II and Species C in the reply filed on 4/25/2007 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-19, 22, 24-32, 35, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Vargas et al. (US 6,371,964).

Vargas discloses:

17. A connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit and a second aperture in a side wall defined by first and second ends of a tubular body tissue conduit in a patient, the connector comprising: a structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (figure 1 item 14 lower part of upper portion 18), the structure including: a first portion (24), wherein

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the first portion includes a plurality of first members extending away from the structure (figure 1 item 14 ; upper part of upper portion 18), wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group of the plurality of first members (figure 1 lower portion 16) is configured to engage the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the first group of first members, wherein a first spacing is defined between at least the first group of first members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Column 3 Line 20).

18. The connector defined in claim 17, wherein the first and second groups of first members are substantially radially aligned with respect to a common axis (figure 1).

19. The connector defined in claim 18, wherein the first members of the first group extend distally away from the first portion of the structure and wherein the first members of the second group extend proximally away from the first portion of the structure (Figure 1).

22. The connector defined in claim 18, wherein the first group of first members at least

includes the second group of first members so that the first group of first members is configured to engage both the graft tissue conduit about the first aperture and the interior wall of the body tissue conduit about the second aperture, so that tissue of the graft tissue conduit can extend from within the lumen the body tissue conduit to outside of the body tissue conduit, and so that body fluid of the patient can flow between the lumen of the graft tissue conduit and the lumen of the body tissue conduit via the connection (functional language with no further structure claimed, no patentable weight over the cited art).

24. A connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit and a second aperture in a side wall defined by first and second ends of a tubular body tissue conduit in a patient, the connector comprising: a hollow structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis and configured for disposition substantially perpendicular to the longitudinal axis of the tubular graft conduit and the tubular body conduit (24), the structure including: a distal axial portion (Figure 1 item 14 lower part of upper portion 18), wherein a plurality of first members (figure 1 item 14 upper part of upper portion 18) extend away from the distal axial portion in an annular array that is substantially concentric with the structure, wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group of the plurality of first members (figure 1

item 14 lower part of upper portion 18) is configured to engage the graft tissue conduit about the first aperture; a proximal axial portion (figure 1 item 14 upper portion of lower part 16), wherein a proximal perimeter is defined by a plurality of second members of the proximal axial portion (figure 1 item 14 lower part of lower portion 16) configured to engage the exterior wall of the body tissue conduit about the second aperture; and a medial axial portion (24 portion not including "structure") between the distal axial portion and the proximal axial portion, wherein an axial spacing is defined between at least the first group of first members and the plurality of second members, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter and a first axial spacing to an expanded configuration having an expanded distal perimeter and a second axial spacing.

25. The connector defined in claim 24, wherein the medial axial portion is configured to extend in a first direction along the exterior of the graft tissue conduit about the first aperture substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

26. The connector defined in claim 24, wherein the distal axial portion is configured to receive tissue of the graft tissue conduit about the first aperture extending up through the hollow interior of the structure in a direction substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

27. The connector defined in claim 24, wherein the collapsed distal perimeter is smaller than the perimeter of the second aperture (the second aperture refers to the tissue graft, the tissue graft has not been specifically claimed so this claim does not add any structural limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

28. The connector defined in claim 24, wherein the second axial spacing is smaller than the first axial spacing (figure 2).

29. The connector defined in claim 24, wherein at least the first group of first members and the plurality of second members are configured to resiliently press the graft tissue conduit and the body tissue conduit into annular contact with one another annularly around the first and second apertures (functional language, structure not differentiated from reference).

30. The connector defined in claim 24, wherein the second axial spacing is substantially equal to the sum of the wall thickness of the graft tissue conduit and the wall thickness of the body tissue conduit (graft tissue and body tissue not specifically part of claimed structure, therefore claim does not include any new limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

31. The connector defined in claim 24, wherein the first and second groups of first members are substantially radially aligned with respect to the longitudinal axis of the structure (figure 1).

32. The connector defined in claim 31, wherein the first members of the first group extend distally away from the proximal axial portion of the structure and wherein the first members of the second group extend proximally toward the proximal axial portion of the structure (figure 1).

35. The connector defined in claim 31, wherein the first group of first members at least includes the second group of first members so that the first group of first members is configured to engage both the graft tissue conduit about the first aperture and the interior wall of the body tissue conduit about the second aperture, so that tissue of the graft tissue conduit can extend from within the lumen the body tissue conduit to outside of the body tissue conduit, and so that body fluid of the patient can flow between the lumen of the graft tissue conduit and the lumen of the body tissue conduit via the connection (functional language with no further structure claimed, no patentable weight over the cited art).

54. Apparatus for producing a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a graft tissue conduit and a second aperture in a side wall defined by first and second ends of a body tissue conduit in a

patient, comprising: a connector having a structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (24), the structure including: a first portion (figure 1 lower part 14 of upper portion 18), wherein the first portion includes a plurality of first members extending away from the structure (figure 1 upper part of upper portion 18), wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group (figure 1 upper part 14 of lower portion) of the plurality of first members is configured to engage the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the first group of first members, wherein a first spacing is defined between at least the first group of first members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Col 3 Line 20); and a delivery tool (Figures 4-6) having a first configuration and a second configuration, wherein the first configuration is configured for retaining a retainable portion of the connector proximal to the first group of first members to deform the connector structure from the expanded configuration to the deformed configuration and to advance the collapsed distal perimeter of the connector into the lumen the body tissue conduit via the second aperture, and wherein the second configuration is configured for releasing the retainable

portion of the connector to reform the connector structure from the deformed configuration to the expanded configuration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 21, 23, 33, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas '964 and Lazarus (US 5,397,345).

Vargas discloses the invention substantially as claimed as stated above. Vargas does not explicitly disclose hooks or barbs on the first members. Lazarus teaches the use of hooks and barbs to engage the tissue or graft wall (Item 70). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Vargas' members to include Lazarus' barbs and hooks. Such a modification would engage the graft material so the vessels remain connected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


LOAN H. THANH
PRIMARY EXAMINER